

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1, 6, 11-13, 18-21, 24-26, and 73 are pending with entry of this amendment. Claims 21 and 73 are amended herein as suggested by the Examiner to overcome claim objections. Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

The Priority Claims are Proper

Benefit of the filing dates of provisional application 60/444,494, filed January 31, 2003, and provisional application 60/519,074, filed November 10, 2003, was not acknowledged by the Examiner. As described in detail in the response filed December 10, 2007 and in the response filed August 8, 2008, Applicants have presented a proper priority claim to both documents and respectfully request that the relevant priority claims be properly acknowledged.

35 U.S.C. §102.

Claims 1, 6, 11-13, 18-21, 24-26, and 73 were rejected under 35 U.S.C. §§102(a) and 102(e) as allegedly anticipated by Timans et al.; under 35 U.S.C. §102(b) as allegedly anticipated by De Sauvage et al. and by Bennet et al.; and under 35 U.S.C. §102(e) as allegedly anticipated by Matthews et al. Applicants respectfully traverse each rejection as provided in the responses filed December 10, 2007 and August 8, 2008, and for the reasons provided below.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. Anticipation requires that “all limitations of the claim are found in the reference, or ‘fully met’ by it.” Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983).

The office has yet to point out where the prior art teaches the steps of administering an IL-27R agonist to a person selected to be in need of immune suppression. Applicant has pointed out where in each cited reference those of skill in the art, i.e., the authors of those references, have advocated the use of IL-27R agonists for immune activation. Applicants have also pointed out that nowhere in those references is it specifically taught to give an agonist of IL-27R for immune suppression. Please see, Applicants' response filed on December 10, 2007 for a thorough description of the art.

Page nine of the office action asserts that Applicants arguments that IL-27R agonists be used for activation and antagonists are used for suppression is not scientifically accurate. This argument comes straight from the cited art (Please see, Applicants' response filed on December 10, 2007 for a thorough description of the art). For example, paragraph 161 of Timans states,

"Taken together the above indicates a role for the composite cytokine and its associated receptor subunit WSX-1/TCCR in inflammatory responses. Therefore antagonizing the function of any of the components in the receptor subunit:ligand complex should have a beneficial effect in inflammatory diseases, e.g., inflammatory bowel disease, rheumatoid arthritis, etc."

This paragraph clearly shows that Timans teaches that an **antagonist** of IL-27R should be used in treatment of an inflammatory response. The claimed methods are drawn to using an **agonist** of IL-27R to treat an inflammatory response and therefore are clearly not anticipated by Timans (or any other cited reference).

However, the Examiner's arguments seem to ignore the cited art. The cited art makes very clear that at the time of Applicants invention IL-27R agonists, e.g., IL-27, were considered useful for immune activation and IL-27R antagonists for immune suppression. Applicants are claiming the exact opposite. Therefore the rejections under 35 U.S.C. § 102 must be withdrawn.

The Examiner references other cytokines that may be used as both antagonists and agonists for both immune suppression and immune activation. Applicants fail to see how a reference regarding IL-6 or TNF teaches using an agonist of IL-27R to suppress the immune system. Even assuming other cytokines have multiple uses, the art must teach this particular use for this particular cytokine as claimed to anticipate the claimed invention. This has not been shown. The mere possibility that some cytokine somewhere could perhaps

serve as both an inflammatory agent and an anti-inflammatory agent, even if true, does not teach the claimed method.

The Examiner also alleges that cytokines are too complicated for applicant to argue that the art is counterintuitive and that the conventional thinking suggests the opposite of what is claimed (see Office action, page 8, line 6). Applicants' argument is not simply that the art is counterintuitive, Applicants' argument is that the art simply does not teach what Applicant claims. Furthermore, it is not "conventional thinking" upon which Applicants rely, it is the actual art cited by the Examiner. The simple fact is that the cited art does not teach what Applicants claim. No amount of complexity in the art can provide this teaching or erase what is clearly stated in the cited art. If the office wishes to persist with this rejection, Applicants request that they state exactly where the art teaches that one should administer an IL-27R agonist to a patient in need of immune suppression or where in the art the steps of this method were inherently performed. This has not been shown and therefore the rejection must be withdrawn.

Furthermore, the Examiner's reliance on the pleiotropic nature of cytokines is irrelevant given the art cited in the action. Despite any inherent properties of IL-27, the cited art teaches administering IL-27R agonists to those in need of immune activation. For more detail on prior art teachings, please see the response filed December 10, 2007. The cited prior art does not teach what is claimed and no amount of extrinsic evidence can rectify that omission. Examiner has cited no art showing that at the time of Applicants' invention, someone had administered IL-27R agonists to a patient in need of immune suppression. The Examiner acknowledged, on page 10, lines 16-18 (quoting In re Robertson), that "to establish inherency the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized by persons of ordinary skill." The extrinsic evidence does nothing to show that administration of IL-27 agonists to those in need of immune suppression was necessarily present in the cited art (Timans, De Sauvage, Bennet, or Matthews).

The Examiner has not shown where in the prior art the claimed method steps are taught and has instead relied on the theory of inherency and cited extrinsic evidence to support that claim. However, the extrinsic evidence directed to IL-27 post-dates Applicants'

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filings date (February 2, 2004) and priority date (January 31, 2003). These references therefore show nothing with regard to what the state of the art was or what one of skill in the art would have known at the time of Applicants' invention.

Although M.P.E.P § 2124 clearly states that extrinsic evidence may be used to show the state of the art at or around the time of the invention was made even if it post-dates the application, Applicants respectfully point out that the evidence must still show the state of the art **at or around the time of the invention**. In the review article by Stumhofer and Hunter relied upon by the Examiner as extrinsic evidence, only 37 out of 87 references in the article date from before 2005. Furthermore, only 11 of those date from before 2004 and relate directly to IL-27, 3 of which are Applicants own art. Applicants respectfully point out that this is not representative of the state of the art at the time of Applicants' invention.

The other review article relied upon for extrinsic evidence (Villarino, Huang, and Hunter), although published in 2004 and relying upon references that are arguably state of the art at the time of filing, was published by Applicants and based on the manuscripts that were filed as provisional applications in this application. It seems somewhat illogical to say that Applicants' manuscripts cannot support a priority claim, but a reference that relies on those manuscripts (see reference 10 of the Villarino and Hunter reference cited by Examiner) can be used against them in an anticipation rejection as evidence of the state of the art.

Until Applicants invention and subsequent publication, the state of the art was to use IL-27R agonists as immune activators. All of the extrinsic evidence related to IL-27 that was cited by the Examiner is Applicants' own evidence, e.g., a recitation of Applicants' invention published after Applicants' application for patent. It may now be the state of the art, but it was not at the time of Applicants' invention.

In In re Wilson and Lieberman 135 U.S.P.Q. 442 and in Ex parte Erlich 22 U.S.P.Q.2d 1463 (two cases cited in the M.P.E.P. for use of extrinsic evidence), extrinsic evidence was used to show state of the art at the time of invention. Even though the references used post-dated applicants' invention, the particular portions relied upon for the rejection were acknowledged by both parties as known at the time of the invention. In the present case, the information relied upon in the post-dated references was not known at the

time of the invention, or if so, only by Applicants which makes it their invention, not state of the art at the time.

In addition, because the IL-27 art relied upon as extrinsic evidence, is Applicant's own art published after their application for patent it seems a gross injustice to consider it state of the art as of the time of their invention. Although it may now be considered state of the art, it can only be so considered for the time period after Applicants' invention as Applicants are responsible for placing it in the art with the disclosure of their invention. At the time of Applicants' invention, (see, e.g., the cited 102 references) those of skill advocated the use of agonists of IL-27R to activate the immune system. It is unfair and somewhat absurd to use Applicants own statements published after their application for patent against them as evidence in a 102 rejection.

Furthermore, the extrinsic evidence used to reject the claimed invention is impermissibly used to expand on the scope of the cited prior art. Applicants respectfully point out that extrinsic evidence can be used to explain the cited art, not to expand on the cited art. See, Ciba Giegy Corp. v Alza Corp. 37 U.S.P.Q.2d 1337 (Fed. Cir. 1995). The prior art cited by the Examiner teaches agonists of IL-27R to activate the immune system. Any other use alleged by the Office is an expansion of what is taught in the art, not a mere explanation.

Even assuming arguendo, that one of skill would have recognized that some cytokines could have pleiotropic properties, nowhere in the prior art was anyone in need of immune suppression explicitly or inherently administered an IL-27R agonist. To do so would have been to disregard the state of the art at the time of the invention, e.g., the art cited as 102 references: Timans, De Sauvage, Bennet, and Matthews.

Applicants acknowledge that agonists of IL-27R are known. What is claimed is a use of those compositions that was not previously contemplated. Although those compounds may have inherent qualities, the method step of administering such a compound to a subject in need of immune suppression was not explicitly or inherently performed in the prior art. Please see Applicants arguments submitted on August 8, 2008 for a complete discussion of the law regarding patenting a new use of a known composition for support of Applicants' position.

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Additional arguments presented by the Examiner in the most recent Office action have yet to show where, in the prior art or in the state of the art at the time of the invention, a patient in need of immune was explicitly or inherently selected for and administered an IL-27R agonist. Applicants' claims are therefore a novel patentable new use for a known compound.

Non-Statutory Obvious-Type Double Patenting

Claims 1, 6, 11-13, 18-23, and 73 were provisionally rejected for alleged non-statutory obvious-type double patenting over claims 21-24 and 26-28 of co-pending application 11/880,121. The Examiner requested that a terminal disclaimer be filed under 37 C.F.R. § 1.321(c) or (d). When all substantive issues have been resolved and the claims are otherwise in condition for allowance, Applicants will submit a terminal disclaimer over the claims of USSN 11/880,121 if it is still necessary at that time.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

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Attachments:

- 1) A petition to extend the period of response for 2 months;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet;
- 4) Notice of Appeal;
- 5) Confirmation of Entity Status;
- 6) McKesson Statement of Relatedness; and
- 7) A receipt indication postcard.